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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,612	03/20/2001	Kanji Takada	AKA-269	4679

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,612	TAKADA, KANJI	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-27* is/are pending in the application.

4a) Of the above claim(s) *20-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-19, 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of the Amendment and the Rule 131/132 Affidavit received on November 7, 2003 is acknowledged. Claims 10-27 are pending in this application. Claims 1-9 are cancelled and claims 20-26 are withdrawn from prosecution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansanobu et al (JP 10226650) in view of Takada (5637319).

Mansanobu discloses glycyrrhizin for various illnesses such as liver disease. However, when treating liver disease a prolonged, successive dosage required. However, intravenous administration gives sharp pain and oral tablets do not provide adequate blood levels since the tablet undergoes first pass metabolism and early decomposition. See page 2 of translation. Masanobu teaches an oral preparation

containing glycyrrhizin and a middle chain fatty acid (capric acid). See page 5. A solubilizing agent such as propylene glycol, polyethylene glycol, or nonionic surfactant is taught. The reference teaches a single dose of 1-500 mg and can be manipulated based on patient. See translation page 10. Further, the reference teaches the oral tablet having an enteric coating to provide target release. The reference exemplifies carboxymethyl ethyl cellulose and the dissolution of the preparation in the large intestine. This allows the drug to be imported to the blood by remaining intact, without degradation in the upper tract of the digestive system. (Note abstract). Further, the reference teaches that absorption promotion by medium-chain fatty acids and salts thereof as absorption promoters is highest in the large intestine. See page 4. Mansanobu teaches a capsule as the preferable dosage form.

Mansanobu does not teach the instant ethylcellulose coating.

Takada teaches an oral controlled release preparation (capsule) to deliver drugs to the lower gastrointestinal tract. The reference teaches the suitability of the dosage form for drugs that need to be delivered to the lower part of the small intestine and/or colon and is especially suitable for drugs that are not to be released in the upper part of the GI tract. See column 3, lines 58-63 and column 5, lines 40-43. The dosage form allows for a sustained release and the gastrointestinal cells are exposed to high concentration of the drug (col. 3, lines 35-50). Takada teaches an ethyl cellulose covered capsule containing a drug composition (Fig. 9). The reference teaches that the thickness of the water soluble membrane and the intestinal pressure control the release

of the material so that the delivery system is site specific and delivers the drug to the large intestine (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Mansanobu and Takada et al and utilize ethylcellulose coating. One would be motivated to do so since Takada teaches a controlled release device that provides target release in the large intestine and is especially suitable for drugs that cannot be released in the upper intestine. Therefore one could reasonably expect similar results since Mansanobu teaches that glycyrrhizin is imported to the blood by having the drug adsorb in the large intestine and the enteric coating acts to avoid degradation in the upper intestine. Furthermore, Mansanobu discloses that successive doses of glycyrrhizin treats liver disease and Takada et al teach a sustained and constant release utilizing an ethylcellulose coating.

In regards to the product-by-process claims, according to the MPEP section 2113 determination of patentability is based on the product itself.

Response to Arguments

Applicant argues that production examples of Mansanobu yield a clear solution and not a shaped core and that the solution is processed into a soft capsule. It is further argued that nowhere does the reference teach a shaped cored which contains glycyrrhizin. Secondly, it is argued that the secondary reference Takada et al does not offer a teaching or suggestion for the preparation of a shaped core.

Applicant's arguments have been fully considered but they are not persuasive. First, the examiner points out that the examples in the instant specification states that

the glycyrrhizin solution/dispersion is poured into a capsule or mold and then cooled to solidified to form the "shaped core". It is pointed out that Masanobu's glycyrrhizin composition is in a molten state and to fill it into the capsule. The composition is capable of solidifying when cooled, as instant invention. Although, the reference does not explicitly state that the solution is solidified when cooled, this is implicit since lipids undergo such as process and clearly the composition is in a melted state to put it into the capsule. It is further pointed out that the instant invention is not distinguishable over the prior art since Masanobu teaches a device for colon delivery with an enteric coating (carboxymethylethylcellulose) and the capsule core is made of glycyrrhizin and fatty acid glyceride.

In regards to claim 27, the recitation of a "coating film" reads on a capsule since Webster's definition of a capsule is "usually medicinal or nutritional preparation for oral use consisting of the shell and its contents."

In regards to the secondary reference, it is pointed out that Takada is utilized for the specific enteric coating. The primary reference teaches the enteric coat may be selected from carboxymethylethylcellulose, HPMC phalate, cellulose acetate, and methacrylic acid copolymers on page 11. Takada teaches the instant ethylcellulose and other polymers such as acrylic and methacrylic acids copolymers, etc for enteric coatings. Therefore, the secondary reference is relied upon to demonstrate the equivalence of the instant enteric coating and the enteric coatings taught in the primary reference.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG
January 14, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER